

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
22 February 2001 (22.02.2001)

PCT

(10) International Publication Number
WO 01/12104 A1

(51) International Patent Classification⁷: A61F 2/01, A61B 17/12

(21) International Application Number: PCT/US00/21645

(22) International Filing Date: 8 August 2000 (08.08.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/374,741 13 August 1999 (13.08.1999) US

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(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

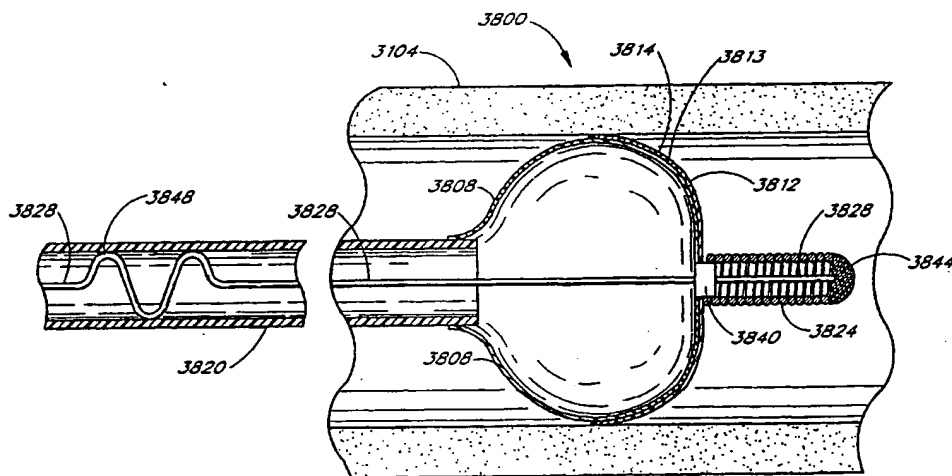
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Published:
— With international search report.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: OCCLUSION OF A VESSEL



(57) Abstract: A device for occluding a vessel employs one of a number of different expansion members joined to one or more elongate members. The expansion member may include a braid, one or more coils, ribs, a ribbon-like structure, a slotted tube, or a filter-like mesh. If the expansion member is enclosed by a suitable membrane, the device seals with the vessel wall to partially or completely occlude the vessel. A perforated membrane may be used to permit the perfusion of blood. The expansion member may be self-expanding, or it may be expanded by engaging it with one of the elongate members. Alternatively, the expansion member may be expanded by heating it.

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OCCLUSION OF A VESSEL

Background of the Invention

Field of the Invention

The present invention relates generally to the occlusion of a vessel within a patient, and more specifically, to an apparatus and method of partially or completely occluding a vessel.

Description of the Related Art

Attempts heretofore have been made to treat occlusions in the carotid arteries leading to the brain. However, such arteries have been very difficult to treat because of the possibility of dislodging plaque which can enter various arterial vessels of the brain and cause permanent brain damage. Attempts to treat such occlusions with balloon angioplasty have been very limited because of such dangers. In surgical treatments, such as endarterectomy, the carotid artery is slit and plaque is removed from the vessel in the slit area. Such surgical procedures have substantial risk associated with them which can lead to morbidity and mortality.

In other procedures, such as in angioplasty and in the treatment of peripheral arteries and veins, there is the possibility that the guide wires and catheters used in such procedures during deployment of the same may cause dislodgement of debris or emboli which can flow downstream and cause serious damage, such as stroke, if they occlude blood flow in smaller vessels. Thus, in summary, embolization and migration of micro-emboli downstream to an end organ is a major concern of cardiologists during catheterizations.

There is therefore need for new and improved apparatus and methods which make it possible to treat occluded vessels without endangering the patient.

Summary of the Invention

The present invention satisfies the need for a device that occludes a vessel, in particular, a vessel in a patient undergoing therapeutic or other medical treatment. Any one of a number of different expansion members are joined to one or more elongate members such as hypotubes to form a device that completely or partially occludes a vessel within a patient. The expansion member may be self-expanding, it may be expanded by engaging it with one of the elongate members, or it may be heated to cause it to expand. A membrane preferably surrounds the expansion member so that a seal is made between the membrane and the vessel. The perfusion of blood is allowed if the membrane is perforated. Partial occlusion may be obtained without a membrane if a suitable expansion member is chosen. In general, in one aspect of the present invention, there is provided an apparatus and method that can be used with approved diagnostic and therapeutic devices to reduce the chance of emboli migrating downstream. Alternatively, the expansion member may anchor an intravascular device within a vessel.

One embodiment of the present invention is a device for occluding a vascular segment, in which the device includes an expansion member and first and second elongate members. The first elongate member engages the expansion member, and the second elongate member surrounds the first elongate member, with the expansion member expanding to occlude the vascular segment when one of the elongate members is moved longitudinally. The expansion member

preferably includes a braid, a coil, a ribbon-like structure, a slotted tube, a plurality of ribs or a filter-like mesh. The device may also include material that adjoins the expansion member for creating a partial or total seal with the vascular segment.

In one particular embodiment, the expansion member is in an unexpanded state when it is surrounded by the second elongate member, but expands when the first elongate member is pushed through the second elongate member. In
5 another embodiment, both the first and second elongate members are secured to the expansion member, and the expansion member expands as the first elongate member is retracted.

Another embodiment of the invention is a method of occluding a segment within a vessel, which includes the step of inserting first and second elongate members into the vessel to be occluded (in which the first elongate member adjoins an expansion member), followed by the step of varying the position of at least one of the elongate members so that the
10 expansion member expands until the vessel is completely or partially occluded. In one embodiment, the varying step includes retracting one of the elongate members, and in another embodiment, the varying step comprises pushing one of the elongate members through the other elongate member.

In yet another method of occluding a segment within a vessel, an expansion member is inserted within the vessel, and the expansion member is heated to cause it to expand until the vessel is at least partially occluded. Heating the
15 expansion member may involve, for example, passing electrical current through it or passing warm solution over or near it.

According to another aspect of the invention, there is provided a method of performing therapy on a vessel, which comprises mechanically expanding an expandable member by longitudinally moving a pull wire relative to a tubular member that surrounds the pull wire. The expandable member is expanded until the expandable member contacts the vessel, and a lock is engaged to maintain the expandable member in substantial contact with the vessel.
20 While the lock is engaged, a plurality of catheters are exchanged over the tubular member. In a preferred embodiment, therapy is performed on the vessel, such as angioplasty, and emboli are collected in the expandable member. The plurality of catheters may include an aspiration catheter and/or an irrigation catheter.

According to still another aspect of the invention, there is provided a method of occluding a segment within a blood vessel, comprising inserting a tubular member into the blood vessel, in which the tubular member has an
25 expandable member at a distal portion thereof. An elongate member is inserted within the blood vessel, in which the elongate member is positioned within the tubular member and operably connected to the expandable member. The expandable member is expanded into contact with the blood vessel by relatively longitudinally moving the tubular member and the elongate member within the vessel. A lock is moved at a proximal portion of the elongate member into a locked position which prevents relative longitudinal movement of the elongate member and the tubular member,
30 so that the expandable member remains in contact with the blood vessel. The lock is maintained in the locked position while a plurality of catheters are exchanged over the tubular member. In one preferred embodiment, the elongate member is retracted to expand the expandable member.

In another aspect of the invention, a device for use in a vessel includes a catheter and a pull wire disposed within the catheter, in which the pull wire contacts a surface of the catheter to provide friction between the pull wire
35 and the catheter. The device also includes an expandable member connected to the pull wire, wherein the expandable

member is deployed to contact the vessel by moving the pull wire relative to the catheter. The pull wire and the catheter are in frictional contact such that the frictional force offsets any relative longitudinal force between the pull wire and the catheter when the expandable member is in an expanded condition, whereby the pull wire and the catheter are frictionally secured together. In a preferred embodiment, the pull wire has at least one bend therein, with
5 the pull wire contacting the catheter at the bend.

According to another aspect of the invention, a method of using a device in a vessel includes inserting into the vessel a catheter to which an expandable member is operably coupled. The expandable member is deployed to contact the vessel by moving a pull wire in the longitudinal direction, in which the pull wire is operably coupled to the expandable member. Frictional forces between the pull wire and a surface of the catheter are utilized to prevent the
10 pull wire from moving in the longitudinal direction, so that the expandable member remains deployed. A force is applied to the pull wire to overcome the frictional forces so that the expandable member returns to an undeployed position. In a preferred embodiment, deploying the expandable member comprises expanding an expandable member to occlude the vessel. In one preferred embodiment, blood is perfused through the expandable member while emboli are captured in the expandable member. In a preferred embodiment, a bend is formed in the pull wire, in which the bend
15 contacts the surface to provide the frictional forces.

Brief Description of the Drawings

FIG. 1 is a side-elevation view in section of one embodiment of a catheter apparatus incorporating the present invention for treating occluded vessels.

FIG. 2 is a side-elevation view in section similar to FIG. 1 but showing the apparatus in FIG. 1 with the expansion
20 member (in this case, a self-expandable seal) deployed.

FIG. 3 is a side-elevation view in section of another embodiment of a catheter apparatus incorporating the present invention for treating occluded vessels.

FIG. 4 is a view similar to FIG. 3 but showing the expansion member (in this case, a self-expandable seal) deployed.
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FIG. 5 is a schematic, longitudinal cross sectional view of an embodiment in which a membrane only partially surrounds a braid used as the expansion member.

FIGS. 6A and 6B show end views of unperforated and perforated membranes, respectively.

FIG. 7 is a schematic, longitudinal cross sectional view of an embodiment in which a braid without a membrane is used.
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FIG. 8 is a schematic, longitudinal cross sectional view of an embodiment in which a filter-like mesh is used as the expansion member.

FIG. 9 is a schematic, longitudinal cross sectional view of an embodiment in which a slotted tube is used as the expansion member.

FIG. 10 is a perspective view of the slotted tube used in the embodiment of FIG. 9.

FIG. 11 is a schematic, longitudinal cross sectional view of an embodiment in which a coil is used as the expansion member, and the proximal end of a membrane surrounding the coil adjoins the coil.

FIG. 12 is a schematic, longitudinal cross sectional view of an embodiment in which a coil is used as the expansion member, and the proximal end of a membrane surrounding the coil adjoins a sheath that surrounds both first and second elongate members.

FIG. 12A is an embodiment similar to that shown in FIG. 12, in which resistive heating is used to expand the expansion member, with current being conducted through wires being attached to either side of the expansion member. The expansion member as shown is partially deployed.

FIG. 12B is an embodiment similar to that shown in FIG. 12A, in which resistive heating is used to expand the expansion member, with current being conducted through a wire being attached to the distal end of the expansion member and through a coating on the first elongate member. The expansion member as shown is partially deployed.

FIG. 13 is a schematic, side cross sectional view of an embodiment in which a plurality of ribbons are used as the expansion member.

FIG. 13A is an embodiment similar to that shown in FIG. 13, in which a warm solution passes between the first and second elongate members to transfer heat to the expansion member, causing it to expand. The expansion member as shown is partially deployed.

FIG. 13B is an embodiment similar to that shown in FIG. 13A, in which a warm solution passes through the first elongate member to transfer heat to the expansion member, causing it to expand. The expansion member as shown is partially deployed.

FIG. 13C is an embodiment similar to that shown in FIGS. 13A and 13B, in which a warm solution passes through one or more lumens in the first elongate member to transfer heat to the expansion member, causing it to expand. The expansion member as shown is partially deployed.

FIG. 14 is a schematic, side cross sectional view of an embodiment in which a plurality of ribs are used as the expansion member.

FIG. 15 is an isometric view of an embodiment of the invention in which a pull wire is used to deploy a plurality of non-self-expanding ribbons surrounded by a membrane.

FIG. 16 is a side partial sectional view of the embodiment of FIG. 15 in which the ribbons are in their relaxed, undeployed position.

FIG. 17 is a side elevation view of the embodiment of FIG. 15 in which the ribbons are deployed, and the membrane makes a seal with the vessel.

FIGS. 18A and 18B show longitudinal and end perspective views, respectively, of a locking mechanism used with a wire that deploys an expansion member.

FIG. 19 is a perspective view of an alternative locking mechanism used with a wire that deploys an expansion member.

FIGS. 20A, 20B, 20C, and 20D show, respectively, a braid, a filter-like mesh, a slotted tube, and a plurality of coils, which can be used as alternative expansion members in place of the ribbons in the embodiment of FIG. 15.

FIG. 21 illustrates a preferred pull wire embodiment for deploying a perfusion-filter.

FIG. 22 illustrates a manifold for retracting a pull wire, thereby deploying the sealing mechanism or
5 perfusion-filter to which the pull wire is attached.

Detailed Description of the Preferred Embodiments

The expansion members discussed herein include braids, coils, ribs, ribbon-like structures, slotted tubes, and filter-like meshes. These expansion members may be partially covered or completely surrounded by a membrane or other covering to provide occlusion or sealing of the vessel. As used herein, "occlusion" or "sealing", and the like, mean partial or
10 complete blockage of fluid flow in a vascular segment, as it is sometimes preferable to allow perfusion. Moreover, such expansion members may be deployed by various mechanical means, electrical means or thermomechanical means, etc., as described herein. Expansion members that are deployed mechanically are preferably "spring-like" in nature, i.e. they are preferably resilient to facilitate their deployment or retraction.

Catheter Apparatuses and Self-Expanding Braids

One embodiment of a catheter apparatus incorporating the present invention for treating occluded vessels is
15 shown in Figures 1 and 2. As shown therein, the catheter apparatus 651 consists of a flexible elongate member 652 which is provided with proximal and distal extremities 653 and 654. A conventional adapter 656 is mounted on the proximal extremity and is provided with a Touhy-Borst fitting 657 which is in communication with a large central lumen 658 extending from the proximal extremity 653 to the distal extremity 654. An aspiration fitting 661 is provided on the
20 adapter 656 as well as an irrigation fitting 662, both of which are in communication with the central lumen 658. However, it should be appreciated that if desired, separate lumens can be provided in the flexible elongate member 652 for both of the fittings 661 and 662.

Self-expanding sealing mechanism 666 is mounted on the distal extremity 654. This self-expanding sealing mechanism 666 can take any suitable form. For example, as shown it can consist of a braided structure 667 formed of a
25 suitable shape memory material such as a nickel titanium alloy that will attempt to expand to a predetermined shape memory. Other than shape memory materials, other materials such as stainless steel, Elgiloy™, titanium or other materials can be utilized in the braid 667 as long as they have the capability of expanding when the self-expanding seal mechanism is released. Also it should be appreciated that the self-expanding seal mechanism 666 can be comprised of an absorbent material which when it absorbs saline or blood expands to form a seal. Such seals can be readily accomplished because it
30 is only necessary to form a seal of approximately 1.5 psi to prevent small particles from moving downstream.

In order to prevent abrasion of a vessel, it is desirable to cover the braided structure 667 with a covering 668 of a suitable material such as a polymer or a biocompatible coating which extends over the braided structure 667 and which moves with the braided structure 667 as it expands and contracts. The polymer can be of a suitable material such as silicone, C-flex, polyethylene or PET which would form a good sealing engagement with the wall of the artery. The
35 covering 668 may be perforated to allow perfusion.

A mechanism is provided for compressing the self-expanding sealing mechanism 666 so that the apparatus can be inserted into the vessel 481 and consists of an elongate sleeve 771 having proximal and distal extremities 772 and 773 and a bore 774 extending from the proximal extremity 772 to the distal extremity 773. A collar 776 is mounted on the proximal extremity 772 of the sleeve 771 and is positioned near the adapter 656. The collar 776 serves as a mechanism for retracting the sleeve as shown in Figure 2 to uncover the self-expanding sealing mechanism 666 after the catheter has been deployed to permit the self-expanding sealing mechanism 666 to expand and form a seal with the arterial vessel adjacent the stenosis to be treated.

Another embodiment of a catheter apparatus for treating occluded vessels incorporating the present invention is shown in Figures 3 and 4. As shown therein, the apparatus 781 consists of a guiding catheter 782 having proximal and distal extremities 783 and 784. As shown, the distal extremity 784 is provided with a pre-formed bend of a conventional type. A conventional attachment 786 is mounted on the proximal extremity 783. Self-expanding seal mechanism 791 is mounted on the distal extremity 784 and is of the type hereinbefore described in connection with the embodiments shown in Figures 1 and 2. A sleeve 796 similar to the sleeve 771 of the previous embodiment is provided in the present embodiment for encasing the self-expanding seal mechanism 791 and for releasing the same after it has been disposed in an appropriate position within a vessel adjacent the occlusion to be treated. Thus, a sleeve 796 is provided having proximal and distal extremities 797 and 798 and having a bore 799 extending from the proximal extremity to the distal extremity which is sized so that it can receive the guide catheter 782. It is provided with a collar 801 on its proximal extremity which is adapted to be disposed outside the patient and which is adapted to be grasped by the physician for pulling the sleeve 796 proximally to uncover the self-expanding seal 791 after the apparatus has been deployed to permit the self-expansion of the sealing mechanism 791 to form a seal with the vessel wall as shown in Figure 4.

In accordance with the hereinbefore described descriptions, it is apparent that the apparatus can be readily deployed and serve the same function as the main catheter. To accomplish this, the assembly 781 can be introduced into the femoral artery and the distal extremity advanced into the desired location in the arterial vessel. After it has been properly positioned, the physician can retract the sleeve 796 to permit the self-expanding seal mechanism 791 to expand and to form a seal with the wall of the arterial vessel to occlude the arterial vessel and interrupt the flow of blood in the vessel to provide a working space distal of the occlusion formed. This prevents small particles which may thereafter be dislodged from moving downstream. Since a central lumen is available, the therapeutic procedures hereinbefore described can be employed with the catheter apparatus shown in Figures 1, 2, 3 and 4.

Although the self-expanding sealing mechanism 666 (791) can be deployed by retracting the sleeve 771 (796) as previously described, the sealing mechanism can also be deployed by pushing the flexible elongate member 652 (guiding catheter 782) through the sleeve so that the sealing mechanism can expand. This may be the preferred way of deploying the sealing mechanism 666 (791), if there is little clearance between the apparatus 651 (781) and the vessel within which the apparatus resides, to reduce the risk of damaging the patient's vessel. As discussed below in connection with subsequent figures, the sealing mechanism 666 (791) may alternatively comprise members such as a coil, a ribbon-like

structure, a slotted tube, or a filter-like mesh. In each case, the sealing mechanism expands to partially or completely occlude the vessel in question, or alternatively, to anchor an intravascular device to the vessel.

Alternative Self-Expanding Members

Another embodiment using a braided structure is shown schematically in FIG. 5, in which a flexible elongate member 20 is disposed within a second elongate member 24 such as a hypotube. A self expanding mechanism 28 such as a braided structure is secured to the distal end of the elongate member 20, preferably within an indentation 32 of member 20. The braided structure 28 is only partially encapsulated by a preferably elastomeric membrane 36 that makes a seal with the patient's vessel 40. (Alternatively, a coating such as a polymeric coating may be used in place of the membranes disclosed herein.) In this and the other embodiments, adhesive may be used to secure the self-expanding mechanism 28 and the membrane 36 to the elongate member 20. In the embodiment of FIG. 5, the braided structure 28 and membrane 36 are designed to be asymmetrical, with more material being concentrated at the proximal side of the structure 28. The braids of the embodiments disclosed herein may be stainless steel 304 or 400, superelastic or heat activated Nitinol, an iron base shape memory alloy, or a polymer base, such as polyethylene or polypropylene. They may be constructed, for example, by using standard equipment such as a braider.

Although the embodiment of FIG. 5 shows the flexible elongate member 20 connected to a guidewire tip 44, other technologies for guiding the device through the patient's vessel 40 may be used in this and the other embodiments, such as a guidewire (either over the wire or single operator) or the exchange catheter method, as is well known in the art. Also, although not explicitly shown in the embodiment of FIG. 5 and the other embodiments herein, these embodiments may include lumens, aspiration and irrigation fittings, and collars like those illustrated in FIGS. 1-4.

The membrane 36 is preferably impervious to the flow of blood (FIG. 6a) for those applications not requiring perfusion, although a perforated membrane 36 (FIG. 6b) having numerous holes 37 therein may be used in other applications to allow the passage of blood. The holes 37 are preferably greater than 10 microns in diameter and may be up to 80 microns or more in diameter to permit the passage of blood cells (nominally 6-10 microns in diameter) through the membrane 36 while blocking larger particulates such as emboli. Likewise, a perforated membrane 36 may be used in the other embodiments disclosed herein. Antithrombogenic coatings can be used (e.g., heparin) to prevent thrombosis formation.

FIG. 7 shows an embodiment in which a braided structure 50 is not enclosed by a membrane. When the braided structure 50 comprises, for example, a diamond mesh pattern in which adjacent wires are separated by about 10-80 microns, the braided structure permits the passage of red blood cells, while blocking the flow of matter that may be undesirable, e.g., emboli or other particulates that may be formed or dislodged during medical procedures. Thus, this embodiment is well suited for applications for which perfusion is required.

Alternative self-expanding media are shown in FIGS. 8 and 9. In FIGS. 8 and 9, a self-expanding filter-like mesh 60 and a self-expanding slotted tube 72, respectively, are surrounded by a membrane 62 that is preferably elastomeric. The filter-like mesh 60 (or slotted tube 72) and membrane 62 are bonded or otherwise secured to a flexible elongate member 64, e.g., to an indentation therein. As with the other self-expanding media disclosed herein, the filter-like mesh 60

(or slotted tube 72) expands from its unexpanded state when the flexible elongate member 64 is pushed through a second elongate member 66, or alternatively, when the second elongate member 66 is retracted over the first elongate member 64. The filter-like mesh 60 (or slotted tube 72) then expands so that the membrane 62 forms a seal with the surrounding vessel 68. A guidewire tip 70 aids in guiding the device through the vessel 68. The filter-like mesh 60 and slotted tube 72 are of a suitable shape memory material such as Nitinol or (304 or 400) stainless steel. The filter-like mesh 60 is fibrous in nature, being somewhat analogous to steel wool. The slotted tube 72 has a lattice-like appearance. The slotted tube 72 may be constructed, for example, by irradiating a thin-walled tube with a laser beam to form holes in the tube in the shape of polygons such as oblong quadrilaterals. An unexpanded, slotted tube 74 is shown in FIG. 10.

FIG. 11 illustrates another embodiment, in which a coil 80 serves as the self-expanding mechanism. The coil 80 may be integrally formed with a first elongate member 82 or be otherwise specially joined to it, e.g., by welding or brazing the coil to the elongate member 82. The coil 80 is surrounded by a membrane 84 that expands with the coil when it is pushed out of a second elongate member 86, or alternatively, when the second elongate member 86 is retracted from the coil 80. Thus, the membrane forms a seal with the surrounding vessel 90. The membrane 84 may be attached directly to the first elongate member 82, or to a member 88 such as a disk that is in turn secured to the coil 80 or the first elongate member 82. A guidewire tip 92 for guiding the device through the vessel 90 may be attached to the first elongate member 82 or to the member 88, if one is used.

An embodiment similar to that shown in FIG. 11 is illustrated in FIG. 12, in which the membrane 84 is secured at the proximal end to a separate sheath 94. In this case, the sheath 94 and the first elongate member 82 are extended together over and through, respectively, the second elongate member 86. Assembly may require preloading the coil 80 through the distal end of the second elongate member 86.

Another embodiment that employs a self-expanding medium is shown in FIG. 13, in which a plurality of ribbons 100 make contact with a membrane 102 while they expand to urge the membrane towards the wall of the vessel 104 where it makes a seal. The ribbons 100 of this embodiment are preferably secured to a first elongate member 106 at both ends of the ribbons, by, for example, gluing them in place. The ribbons may be 0.001-0.004" x 0.005-0.020" x 0.25-1.0" strips of Nitinol, stainless steel, or Elgiloy™ which expand when urged out of the second elongate member 108. A guidewire tip 110 may be used for guiding the device through the vessel and is preferably secured to the distal end of the first elongate member 106.

FIG. 14 illustrates an embodiment similar to the one in FIG. 13, in which ribs 120 such as wires form a series of semicircular arcs when they expand. The ribs 120 are surrounded by a membrane 122 that expands with the ribs to form a seal with the vessel 124. The number of ribs 120 is preferably at least three. The ribs 120 are preferably attached directly to a first elongate member 124 that is surrounded by a second elongate member 126. The ribs 120 themselves are preferably made of a shape memory material such as Nitinol or stainless steel. A guidewire tip 128 aids in guiding the device through the vessel 130.

As in the other self-expanding embodiments, the self-expanding mechanism 100 (120) is in an unexpanded state when enclosed by the second elongate member 108 (126), and expands when pushed or pulled beyond the second elongate member 108 (126).

Non-self-expanding embodiments

5 1. Heat activated embodiments

FIGS. 12A and 12B illustrate how electrical means can be used to generate heat to expand an expansion member. A first elongate member 82 (and a coil 80 which adjoins it, coil 80 and member 82 being similar to their unprimed counterparts) is preferably made of heat activated Nitinol, an iron base shape memory alloy, or another material that expands when exposed to heat. As shown in FIG. 12A, low profile, low resistivity electrical lines 81 and 83 preferably
10 pass either through or along the second elongate member 86 and are attached (e.g., soldered) to the first elongate member 82 on either side of the coil 80. When current is applied through the electrical lines 81 and 83 (the power supply is not shown but is preferably outside the patient), the coil 80 heats up through resistive heating, and the coil expands to urge the membrane 84 to contact the vessel wall 90. Alternatively, as shown in FIG. 12B, the first elongate member 82 may have a coating 85 of gold or silver. In this embodiment, the coated elongate member 82 is used to pass current (with most
15 of the current preferably being carried by the coating 85, so that most of the energy is deposited in the coil 80), with the circuit being completed with a low resistivity wire 87 that is preferably connected (e.g., soldered) to either the second elongate member 86 or the sheath 94. This principle of resistive heating to expand a expansion member can be applied to the other embodiments disclosed herein as well.

FIGS. 13A, 13B, and 13C illustrate how heat transfer using a liquid can deploy an expansion member. The
20 ribbons 100 are preferably made of heat activated Nitinol, an iron base shape memory alloy, or another material that expands when exposed to heat. In the embodiment of FIG. 13A, a warm saline solution 107 is passed between the first and second elongate members 106 and 108 and then over the membrane 102, so that heat is transferred to the ribbons 100. As the ribbons 100 heat up, they expand, thereby urging the membrane 102 against the vessel wall 104. As illustrated in FIG. 13B, the warm saline solution 107 may also be passed through the first elongate member 106 and then
25 through holes 109 in member 106 so that the saline solution 107 more directly transfers heat to the ribbons 100. In this embodiment, one or more holes 111 in the membrane 102 (distal to where the seal with the vessel wall 104 is made) may be used to allow the saline solution 107 to flow away beyond the ribbons 100 after heat transfer to the ribbons occurs. As illustrated in FIG. 13C, the saline solution 107 may also be passed through one or more closed loop coils or lumens 113 within the first elongate member 106. In this way, the ribbons 100 and the patient's blood are not exposed directly to any
30 solution. Using heat transfer can also be applied to the other embodiments disclosed herein, provided the expansion member is suitably constructed.

2. Mechanically deployed embodiments

Other non-self-expanding sealing mechanisms that can be used for occluding a vessel are described below. In the embodiment of FIGS. 15-17, a first elongate member 140, preferably a pull wire, is (when the device is completely
35 assembled) attached to a brace member 144 that is in turn attached to a first ring member 148. Adjoining the first ring

member 148 and a second ring member 152 are a plurality of ribbons 156 that extend between the two ring members. Surrounding the ribbons 156 is a membrane 160 that forms a seal with the patient's vessel 162 when the ribbons are expanded. The membrane 160 is joined to at least one and preferably both of the ring members 148 and 152. The membrane 160 can be joined to only one of the ring members 148 and 152, for example, when the membrane 160 extends far enough in the longitudinal direction to permit the membrane to make a good seal with the vessel 162 when the ribbons 156 are deployed. In this case, the membrane 160 does not completely encapsulate the ribbons 156.

To assemble the device, the first and second ring members 148 and 152, the ribbons 156, and the membrane 160 are placed as a unit around a second elongate member 166, which has a pair of oppositely facing holes 170 and 172. The brace member 144 is inserted through the holes 170 and 172 and secured to both the pull wire 140 and the first ring member 148. Further, the second ring member 152 is secured to the second elongate member 166. This assembled configuration, with the ribbons 156 in their longitudinal orientation, is illustrated in FIG. 16. As illustrated in FIG. 17, when the pull wire 140 is retracted, the ribbons 156 (shown in phantom) and the membrane 160 that surrounds them are urged towards the vessel 162, where the membrane contacts and makes a seal with the vessel. The ribbons 156 are preferably resilient enough so that they return to their longitudinal orientation when the pull wire 140 is released. The elasticity and resilience of the pull wire 140 also helps the ribbons 156 return to their undeployed configuration. A guidewire tip 171 may be used to assist in guiding the device to the desired location in the vessel 162.

A preferred way of retracting the pull wire 140 is shown in FIGS. 18A and 18B. FIG. 18A shows the pull wire 140, which is attached to the brace member 144. A rotatable handle 180 is attached to a locking member 184 which in turn is fastened to the pull wire 140. As seen most clearly in FIG. 18B, the locking member 184 and the handle 180 are dimensioned such that they do not extend beyond an outer surface of the elongate member 166, i.e., they do not extend radially beyond the outer periphery or circumferential extent of the elongate member 166. When the locking member 184 clears the tubular, second elongate member 166 within which it resides (which is preferably outside the patient), the locking member and rotatable handle 180 may be oriented as illustrated in FIG. 18B to keep the pull wire 140 taught, thereby preventing relative longitudinal movement of the pull wire 140 and the elongate member 166, so that the sealing mechanism does not return to its undeployed position. The pull wire 140 may be made of stainless or nitinol and may have a diameter of 0.006-0.008 inches, for a catheter having an O.D. of 0.014", for example. After performing a medical procedure such as angioplasty near the mechanically occluded segment of the vessel, the pull wire 140, the elongate member 166, and the sealing mechanism (the ribbons 156 and the membrane 160) may be retrieved from the vessel.

An alternative to the deployment apparatus illustrated in FIGS. 18A and 18B is shown in FIG. 19, in which a handle member 190 is grasped by the clinician to retract the pull wire 140, thereby deploying the sealing mechanism. Once extended, the sealing mechanism preferably has the tendency to return to its undeployed position, which in the process pulls the pull wire 140 back into the second elongate member 166. This can be prevented by inserting a spacer member 194 between the handle member 190 and the second elongate member 166. After the medical procedure is complete, and occlusion of the vessel is no longer required, the spacer member 194 can be removed and the pull wire 140 and the sealing mechanism returned to their respective undeployed positions. The device can then be removed from the patient.

Although the principle of using a non-self-expanding mechanism has been illustrated in FIGS. 15-17 with respect to deformable ribbons, other non-self-expanding mechanisms, as illustrated in FIGS. 20A-20D, can be employed in conjunction with the brace member 144 and the first and second ring members 148 and 152. For example, instead of using ribbons 156, a non-self-expanding braided structure 200 can be used, in which the braided structure 200 adjoins first and second ring members 148 and 152 and is covered with a membrane 160 to form the unit 204 shown in FIG. 20A. The unit 204 can be used in conjunction with an elongate member 166, a brace member 144, a guidewire tip 171, a first elongate member 140 such as a pull wire, a rotatable handle 180, and a locking member 184 to form a device analogous to the ribbon-based device of FIG. 15. Alternatively, other mechanisms can be used for securing the pull wire 140, such as a handle member 190 and a spacer member 194.

Other non-self-expanding mechanisms such as a filter-like mesh 208, a slotted tube 212, and coils 216 can be used to form units 220, 230, and 240 analogous to the braided structure unit 204 as shown in FIGS. 20B, 20C, and 20D. Units 220, 230, and 240 can likewise be used to construct devices analogous to the ribbon-based device illustrated in FIGS. 15-19. Further, if unit 204 is used without a membrane, it may assist in blood perfusion if the braided structure 200 is suitably constructed. Alternatively, perforated membranes like membranes 36 of FIG. 6B may be used to permit blood perfusion. Although the ribbons 156, the braided structure 200, the filter-like mesh 208, the slotted tube 212, and the coils 216 must be actively deployed (e.g. with a pull wire 140), they are nevertheless similar to their self-expanding counterparts.

Another embodiment showing aspects of a preferred pull wire apparatus is shown in FIG. 21. A plurality of ribbons 3808 are joined to a membrane 3812 having holes (not shown) therein. The ribbons 3808 and the membrane 3812 form a deformable, expandable member 3800 which captures emboli while permitting blood to perfuse through and distal to the expandable member. Emboli are captured as blood flows towards that surface 3813 of the membrane 3812 which faces the blood flow (the proximally facing surface), with blood exiting the distally facing surface 3814 of the membrane, leaving the emboli behind.

The ribbons 3808 of FIG. 21 may advantageously be formed from Ni-Ti, stainless steel, or elgiloy, and have a length between 6 mm and 30 mm, and more preferably between 15 and 25 mm. The cross section of the ribbons 3808 may advantageously be 0.003-0.020" in one dimension by 0.009-0.040" in the other. The number of ribbons 3808 is preferably between 4 and 8, although more or fewer ribbons may be used. The membrane 3812 may advantageously include a plurality of holes whose size is chosen such that blood may pass through the holes as blood travels in a distal direction through the vessel 3104, whereas emboli in the blood are too large to pass through the holes and are thereby contained. The emboli are captured by that surface of the membrane 3812 facing the blood as blood flows in a proximal to distal direction. The membrane 3812 may be PET or an elastomeric or plastic material having holes between 20 and 300 microns in diameter, and more preferably between 50 and 100 microns in diameter. The membrane 3812 advantageously makes a seal with the vessel 3104 so that emboli can not pass distal of the expandable member 3800.

A tip 3824 distal to the ribbons 3808 preferably includes radiopaque material to aid the practitioner in positioning the expandable member 3800 within the vessel 3104. The ribbons 3808 of FIG. 21 are deployed with a pull wire 3828, the proximal end of which extends outside of the patient. If a 0.014" O.D. tubular, elongate member 3820 is used, the pull wire 3828 may advantageously have an O.D. of 0.007" (and may be made of Teflon coated stainless steel or Ni-Ti, for example).

The elongate member 3820 surrounds the pull wire 3828 and is attached to the ribbons 3808 at their proximal end. The pull wire 3828 is advantageously attached to a plug 3840 that is secured to the ribbons 3808 at their distal end (e.g., by bonding), so that when the pull wire 3828 is retracted relative to the elongate member 3820, the plug 3840 urges the ribbons 3808 to expand in a radial direction. The relative position of the elongate member 3820 and the pull wire 3828 is varied until the vessel is occluded. The ribbons 3808 bow outwards towards the wall of the vessel 3104, so that the expandable member 3800 seals with the vessel 3104 (i.e., in its deployed position, the expandable member prevents emboli from moving downstream). The radial expansion of the ribbons 3808 may be facilitated by advantageously imparting an initial curvature to the ribbons through heat setting. The pull wire 3828 may advantageously extend within the distal tip 3824 beyond the plug 3840 and terminate in a solder joint 3844 at the distal end of the distal tip. The proximal end of the distal tip 3824 may be advantageously secured to the plug 3840.

After the expandable member 3800 is deployed, the ribbons 3808 tend towards their relaxed, undeployed position in the absence of a restraining force (unless the expandable member 3800 is self-expanding, in which case the expandable member has a tendency to remain in the deployed position). To prevent this, the pull wire 3828 has one or more bends 3848 formed therein for contacting the inner wall of the elongate member 3820, thereby providing frictional forces which keep the expandable member 3800 in its expanded, deployed position. Specifically, the frictional force between the pull wire 3828 and the elongate member 3820 is sufficient to offset or compensate for the spring force provided by the ribbons 3808, which would otherwise urge the ribbons towards their relaxed position. Whereas 0.5-1 pound of pulling force may be required to deploy the expandable member 3800, the friction between the pull wire 3828 and the elongate member 3820 may be sufficient to restrain up to 3 pounds of pulling force. Thus, the bends 3848 of the pull wire 3828 engage the elongate member 3820 to form a compact device for restraining the pull wire from unwanted longitudinal motion. The bends 3848 of the pull wire 3828 may be formed, for example, by coining or by forming a spring in the pull wire. The bends 3848 thus act as a locking member which inhibits movement of the pull wire 3828, and the pull wire 3828 and the elongate member 3820 are frictionally secured together.

The pull wire features of the embodiment of FIG. 21 can also be used if the expandable member 3800 is shape set so that it tends toward an expanded, deployed position in the absence of any applied forces (self-deploying). In this case, the expandable member 3800 may be inserted in the vessel 3104 of the patient in its low profile position, with frictional forces between the pull wire 3828 and the elongate member 3820 preventing the expandable member from expanding. The expandable member 3800 may then be deployed by urging the pull wire 3828 in the proximal,

longitudinal direction (retracting the pull wire) with sufficient force to overcome the frictional forces between the pull wire 3828 and the elongate member 3820, thereby moving the locking member 3848 out of its locked position. Although illustrated with respect to ribbons 3808, the pull wire features of the embodiment of FIG. 21 may be advantageously combined with any of the expandable members disclosed herein.

5 Regardless of whether the expandable member is of the shape set variety (self-expanding) or is undeployed when relaxed, the degree to which the expandable member is deployed can be monitored by noting the longitudinal position of the pull wire 3828. This allows the user to carefully control the extent to which the expandable member is deployed, and is illustrated with respect to one preferred embodiment in FIG. 22. A manifold 3900 for holding the elongate member 3820 and pulling the pull wire 3828 includes two halves 3904, 3908 preferably formed of metal,
10 medical grade polycarbonate, or the like. The halves 3904, 3908 are attached by at least one hinge (not shown), so that the halves are separated and joined in a clam shell manner. A locking clip 3916 secures the two halves 3904, 3908 while the manifold 3900 is in use. A groove (not shown) having a width selected to accept the elongate member 3820 may be used, or alternatively, the elongate member be held in place by clips 3832 having respective slots 3834 therein. One or more pads 3836 glued or otherwise fastened to the bottom half 3904 act in combination with one or
15 more pads (not shown) glued or otherwise fastened to the top half 3908 to keep the elongate member 3820 from sliding when the manifold 3900 is in the closed position. The pads 3836 may be C-Flex or Pebax and be 0.5" long, 0.25-0.5" wide, and 0.125-0.25" thick. A knob 3841 on the top half 3908 of the manifold 3900 is connected to a cam mechanism (not shown) for moving one or more additional pads (which are not shown, but are secured within and protrude slightly from the bottom side of the top half 3908) for positioning and aligning the pull wire 3828. The knob
20 3841 may advantageously move the pull wire 3828 between 3 mm and 20 mm (as indicated by a dial 3845), thereby controlling the extent to which the expandable member is deployed. After deployment of the expandable member, the manifold 3900 may be removed to allow for the passage of a therapy device.

 The locking devices of FIGS. 18A-B and FIG. 21 may be advantageously used in a catheter exchange method in which the tubular, elongate member 166 (3820) functions as a guidewire. Catheters can be advanced over the
25 tubular member 166 (3820) by inserting the proximal end of the tubular member into a distal end of a lumen of the catheter. In one preferred method, the tubular member 166 (3820) is introduced into a vessel such that its distal end is distal of an occlusion to be treated. An over-the-wire therapy catheter (not shown) having an angioplasty balloon at its distal end is advanced over the tubular member 166 (3820) until the balloon is positioned at the occlusion. An expandable device 3800 at the distal end of the tubular member 166 (3820) is mechanically actuated to occlude the
30 vessel distal to the treatment site. Angioplasty is performed to open a stenosis at the treatment site while the vessel is occluded by the expandable device 3800, e.g., by the expanded ribbons 156 (3808) surrounded by the membrane 160 (3812). The expandable device 3800 prevents emboli and other debris formed as a result of the therapy procedure from migrating downstream. The membrane 160 (3812) preferably allows for the perfusion of blood, while entraining or capturing larger particles.

After the angioplasty procedure is completed, the therapy catheter is withdrawn back over the tubular member 166 (3820) and removed from the tubular member and the vessel. An over-the-wire aspiration and/or irrigation catheter is then introduced into the vessel by riding the aspiration (or irrigation) catheter over the tubular member 166 (3820) such that the tubular member is within a lumen of the catheter. With the expandable device 3800 still deployed and the locking mechanism in its locked position, the aspiration (irrigation) catheter is advanced over the tubular member to the treated site, so that the distal end of the catheter is at a location distal to the treated occlusion and proximal to the expandable device 3800. Suction is then applied at the proximal end of the catheter to remove emboli and other debris from the treated site, e.g., particles that are lodged against the proximally facing surface 3813 of the membrane 3812. Such suction creates a distal to proximal blood flow through the lumen of the aspiration catheter and a proximal to distal blood flow in the annular region between the catheter and the blood vessel. (If the expandable device 3800 has holes therein for the perfusion of blood, such suction may also create distal to proximal blood flow through the expandable device.) The site may, if desired, also be irrigated through the aspiration catheter by applying irrigation fluid rather than suction at the proximal end. While the preferred method involves exchange of an angioplasty catheter and an aspiration catheter, it will be understood that any number of catheters may be exchanged without deactivating the expandable device (3800).

The foregoing exchange of catheters is facilitated by the locking member 184 (3848) on the proximal end of the pull wire 140 (3828), which does not extend radially outwardly beyond the outer periphery or circumferential extent of the tubular member 166 (3820). Accordingly, when the locking member 184 (3848) is in its locked position, the lock lies within the profile of the tubular member 166 (3820), thereby permitting the catheters to be slid over the tubular member without unlocking or otherwise disturbing the lock (i.e., without changing the lock's position).

After all of the desired catheters have been utilized and removed, the expandable device 3800 is collapsed and the tubular member 166 (3820) is withdrawn from the vessel. Thus, the expandable member 3800 is expanded prior to initiation of any treatment which may dislodge occlusive material and create emboli, and the expandable device 3800 is not collapsed until preferably all emboli have been removed or captured.

It should be understood that the scope of the present invention is not be limited by the illustrations or the foregoing description thereof, but rather by the appended claims, and certain variations and modifications of this invention will suggest themselves to one of ordinary skill in the art.

WHAT IS CLAIMED IS:

1. A device for use in a vessel, comprising:
a catheter;
a pull wire disposed within said catheter, said pull wire contacting a surface of said catheter to
5 provide friction between said pull wire and said catheter;
an expandable member connected to said pull wire, wherein said expandable member is deployed to
contact the vessel by moving said pull wire relative to said catheter; and
wherein said pull wire and said catheter are in frictional contact such that the frictional force
offsets any relative longitudinal force between said pull wire and said catheter when said expandable
10 member is in an expanded condition, whereby said pull wire and said catheter are frictionally secured
together.
2. The device of Claim 1, wherein said expandable member makes a seal with the vessel when said
expandable member is deployed.
3. The device of Claim 1, wherein said pull wire has at least one bend therein, said pull wire
15 contacting said catheter at said bend.
4. A medical device, comprising:
an elongate tubular body having a proximal end and a distal end and a lumen extending
therethrough;
an expandable member attached to the tubular body, the expandable member having a proximal end
20 and a distal end, the proximal end being connected to the distal end of the tubular body; and
a pull wire extending through the lumen of the tubular body, the pull wire having a proximal end
and a distal end, the distal end of the pull wire being connected to the distal end of the expandable member;
wherein varying the relative position of the pull wire and the elongate body causes the expandable
member to vary between a deployed and undeployed configuration; and
25 wherein the pull wire includes a locking member at its proximal end, the locking member frictionally
contacting the inner wall of the lumen of the tubular body to maintain the relative position of the pull wire
and the elongate body when the expandable member is in either its deployed or undeployed configuration.
5. The medical device of Claim 4, wherein the expandable member includes a plurality of ribbons
joined to a membrane.
- 30 6. The medical device of Claim 5, wherein the ribbons are formed from nickel titanium.
7. The medical device of Claim 6, wherein the ribbons tend toward a relaxed, undeployed position
when the expandable member is deployed in the absence of a restraining force.
8. The medical device of Claim 5, wherein the membrane includes a plurality of holes.
9. The medical device of Claim 4, wherein the locking member includes one or more bends in the pull
35 wire.

10. The medical device of Claim 9, wherein the bends are formed by coining the proximal end of the pull wire.
11. The medical device of Claim 5, wherein the longitudinal position of the pull wire relative to the tubular body controls the extent to which the expandable member is deployed.
- 5 12. The medical device of Claim 5, wherein the expandable member is self-expanding.
13. The medical device of Claim 5, wherein the locking member does not extend radially outward beyond the outer periphery of the tubular member.
14. A method of actuating and deactuating an expandable member on a catheter, comprising:
providing a catheter having an expandable member operably coupled thereto;
10 actuating the expandable member by moving a pull wire in the longitudinal direction, the pull wire being operably coupled to the expandable member;
utilizing frictional forces between the pull wire and a surface of the catheter to prevent the pull wire from moving in the longitudinal direction, so that the expandable member remains deployed; and
applying a force to the pull wire to overcome the frictional forces so that the expandable member
15 returns to an undeployed position.
15. The method of Claim 14, said actuating the expandable member comprising deforming the expandable member.
16. The method of Claim 14, comprising forming a bend in the pull wire, the bend contacting the surface to provide the frictional forces.
- 20 17. A method of performing therapy on a vessel, comprising:
mechanically expanding an expandable member by longitudinally moving a pull wire relative to a tubular member that surrounds the pull wire;
expanding the expandable member until the expandable member contacts the vessel;
engaging a lock to maintain the expandable member in substantial contact with the vessel; and
25 exchanging a plurality of catheters over the tubular member while the lock is engaged.
18. The method of Claim 17, wherein said longitudinally moving a pull wire comprises retracting the pull wire.
19. The method of Claim 17, comprising performing therapy on the vessel.
20. The method of Claim 19, comprising collecting emboli in the expandable member.
- 30 21. The method of Claim 19, said therapy including performing angioplasty on the vessel.
22. The method of Claim 17, wherein at least one of the catheters is a therapy catheter.
23. The method of Claim 22, wherein the plurality of catheters includes an aspiration catheter.
24. The method of Claim 22, wherein the plurality of catheters includes an irrigation catheter.
25. The method of Claim 17, comprising perfusing blood during said occluding.
- 35 26. A method of occluding a segment within a blood vessel, comprising:

inserting a tubular member into the blood vessel, the tubular member having an expandable member at a distal portion thereof;

inserting an elongate member within the blood vessel, the elongate member positioned within the tubular member and operably connected to the expandable member;

5 expanding the expandable member into contact with the blood vessel by relatively longitudinally moving the tubular member and the elongate member within the vessel;

 moving a lock at a proximal portion of the elongate member into a locked position which prevents relative longitudinal movement of the elongate member and the tubular member, so that the expandable member remains in contact with the blood vessel; and

10 maintaining the lock in the locked position while exchanging a plurality of catheters over the tubular member.

27. The method of Claim 26, in which said longitudinally moving comprises retracting the elongate member.

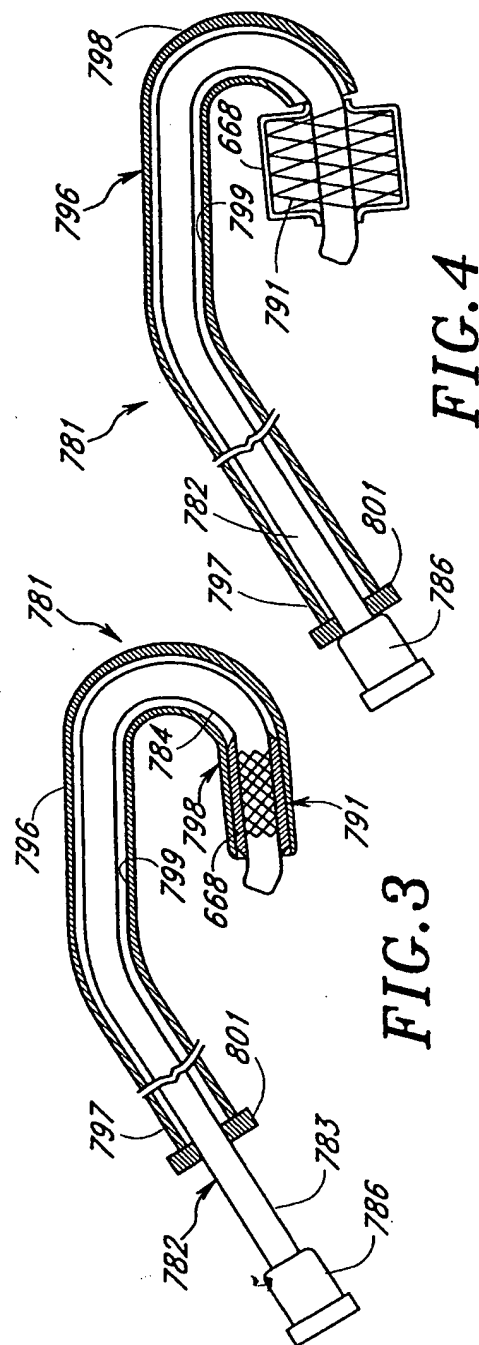
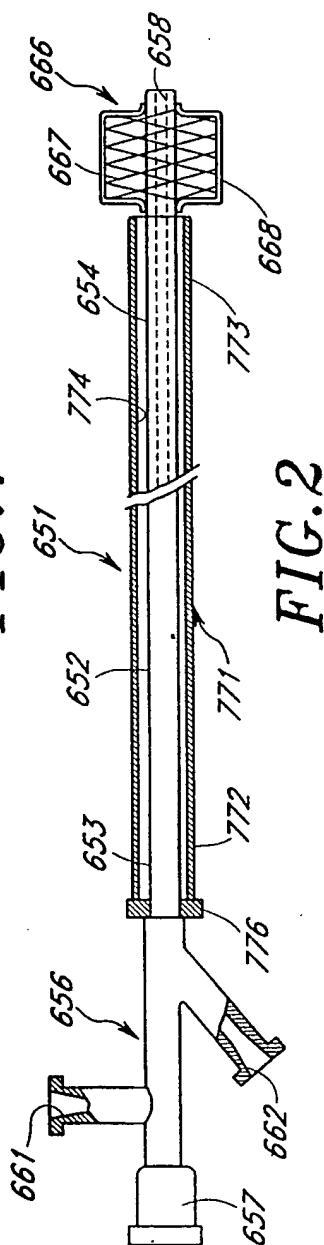
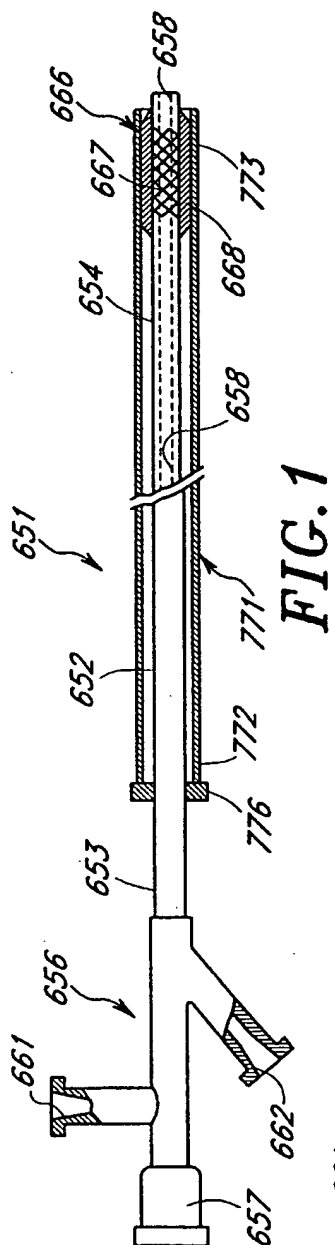
28. The method of Claim 27, in which said retracting causes the expandable member to expand.

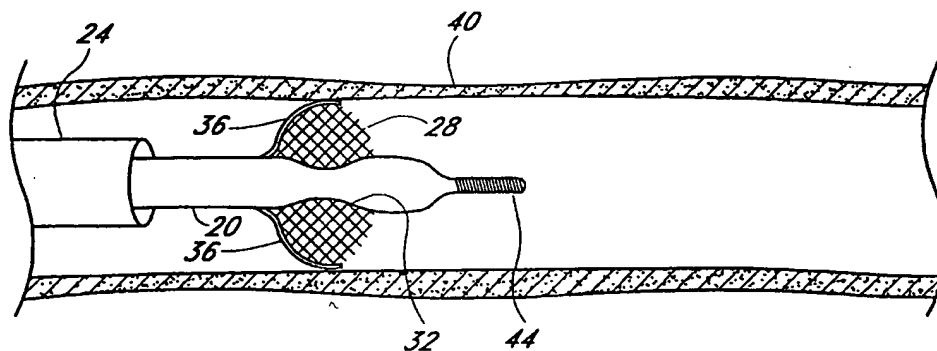
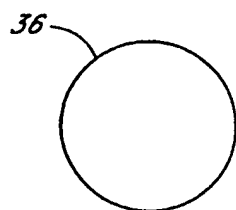
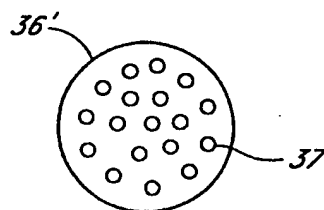
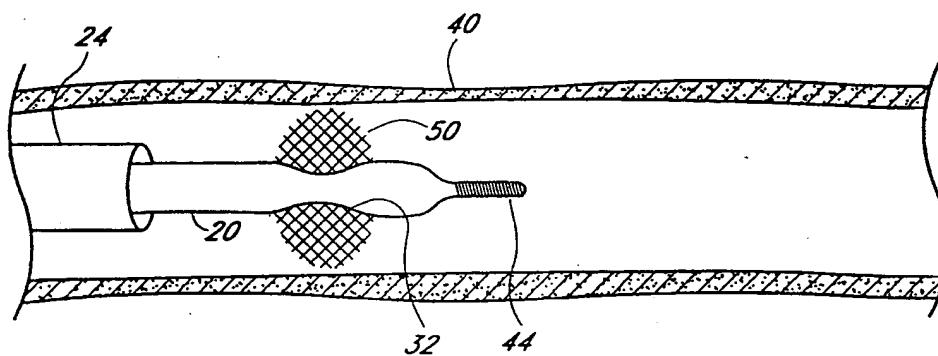
15 29. The method of Claim 27, in which the relative position of the elongate member and the tubular member is varied to expand the expandable member until the vessel is occluded.

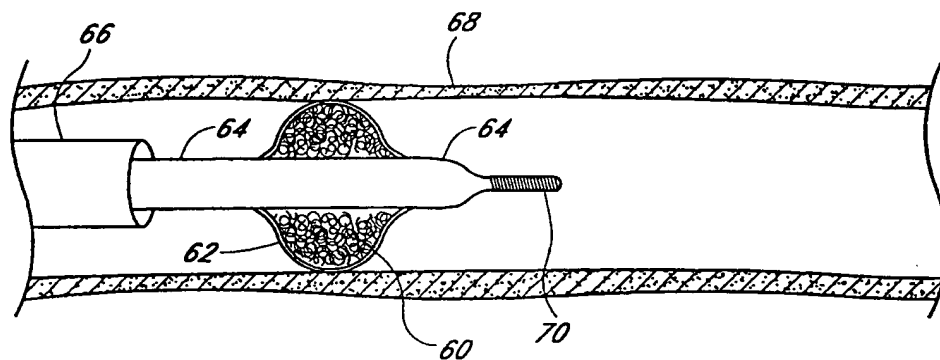
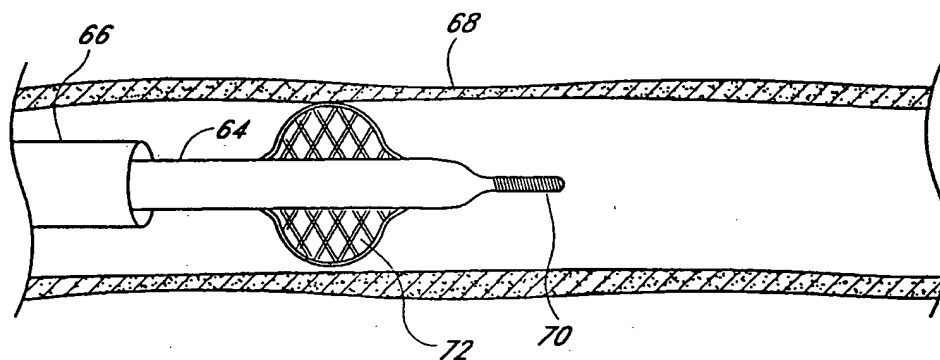
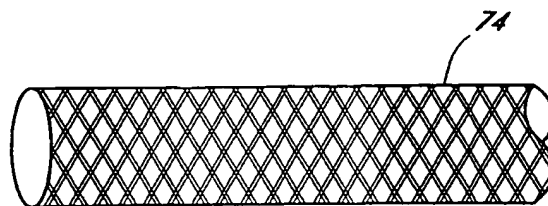
30. The method of Claim 29, further comprising:

 performing a medical procedure near the occluded site; and

 retrieving the elongate member, the tubular member and the expandable member from the vessel.



*FIG. 5**FIG. 6A**FIG. 6B**FIG. 7*

*FIG. 8**FIG. 9**FIG. 10*

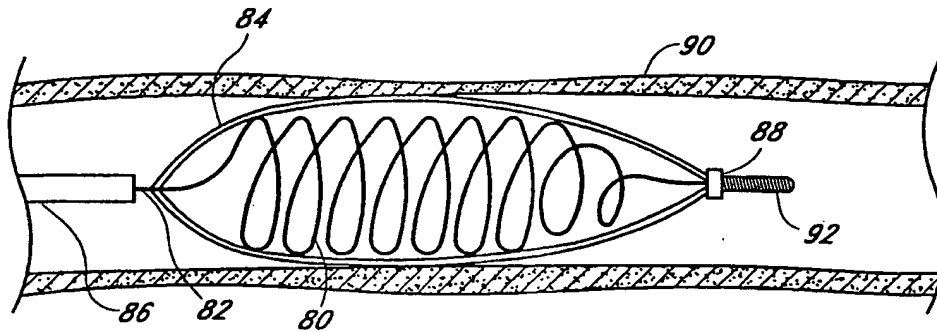


FIG. 11

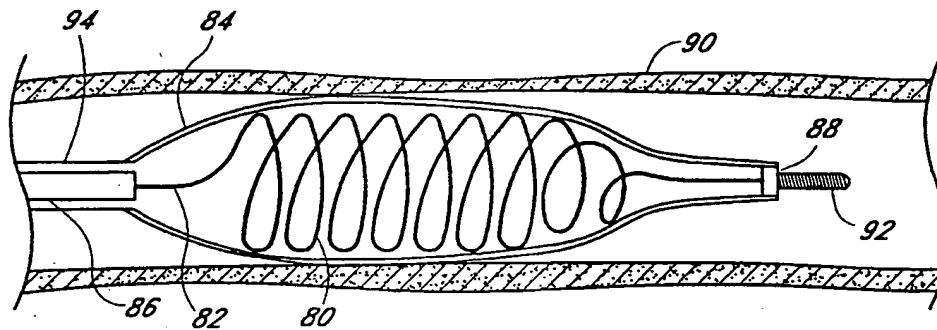


FIG. 12

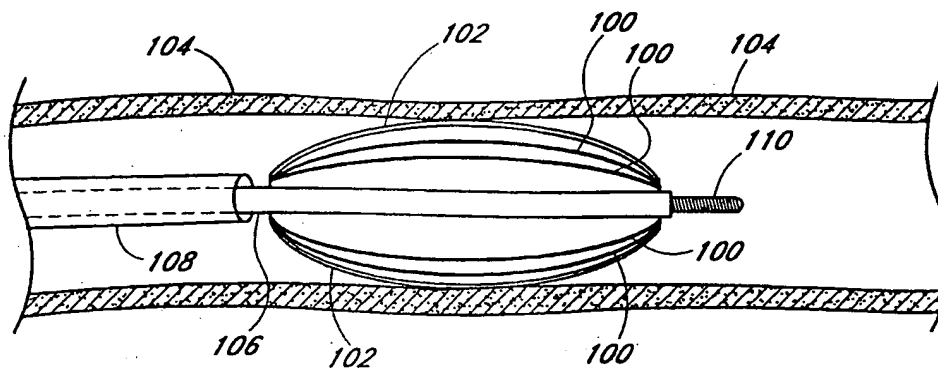
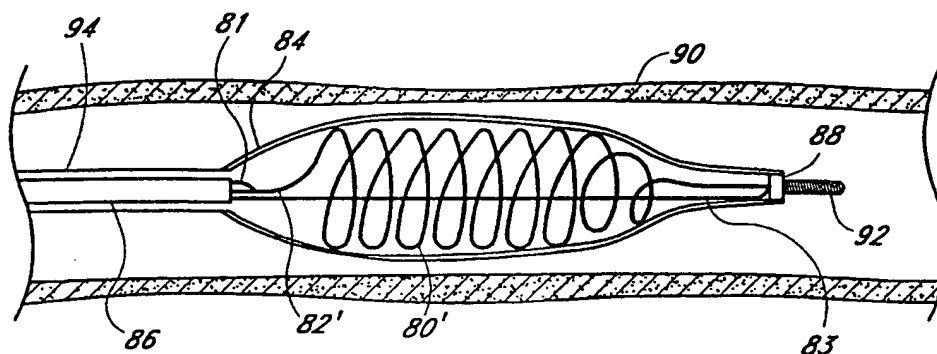
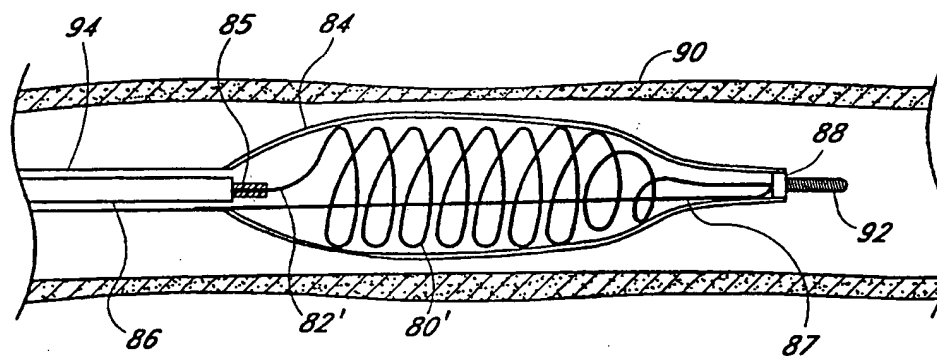


FIG. 13

*FIG. 12A**FIG. 12B*

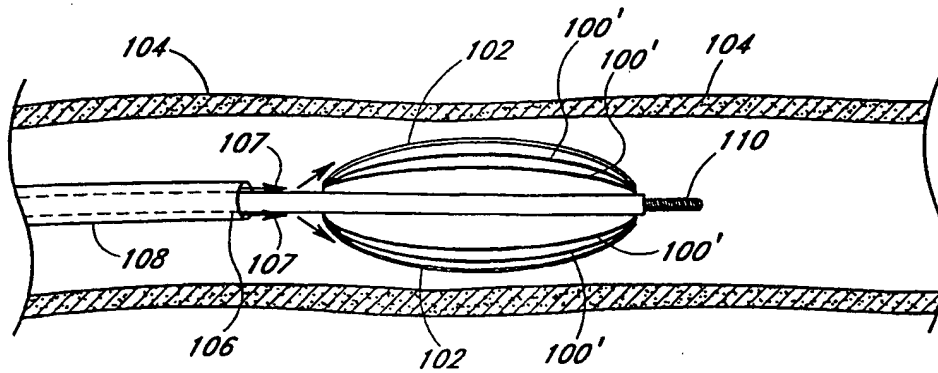


FIG. 13A

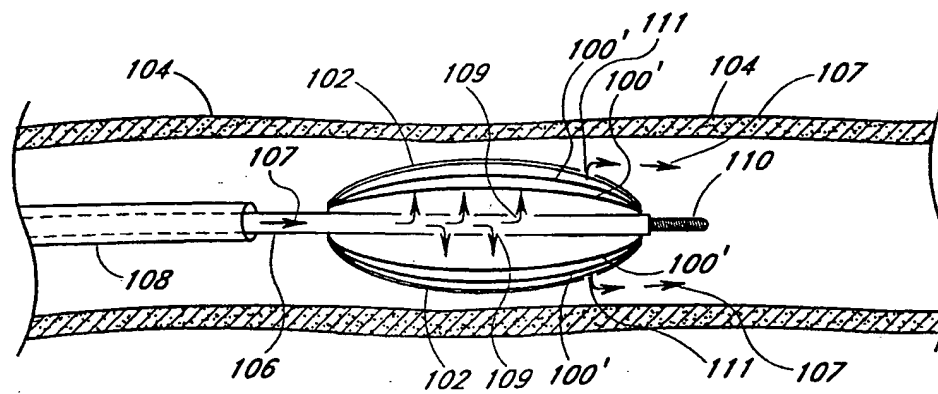


FIG. 13B

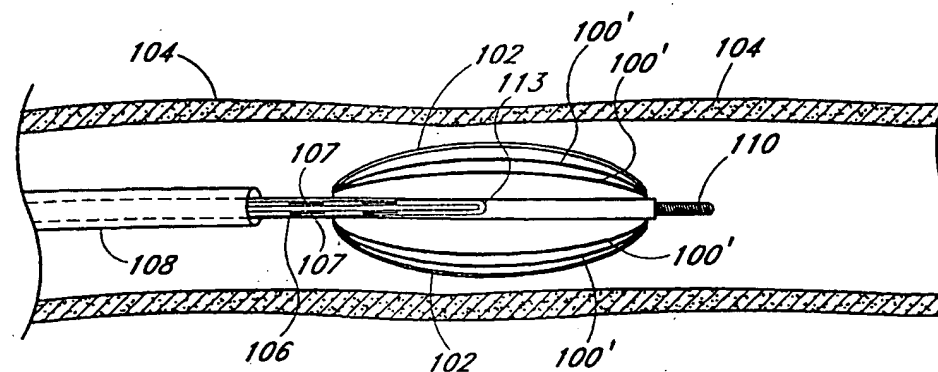


FIG. 13C

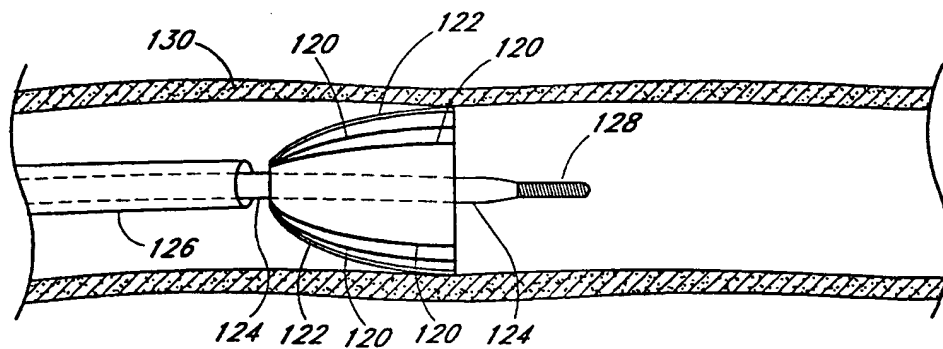


FIG. 14

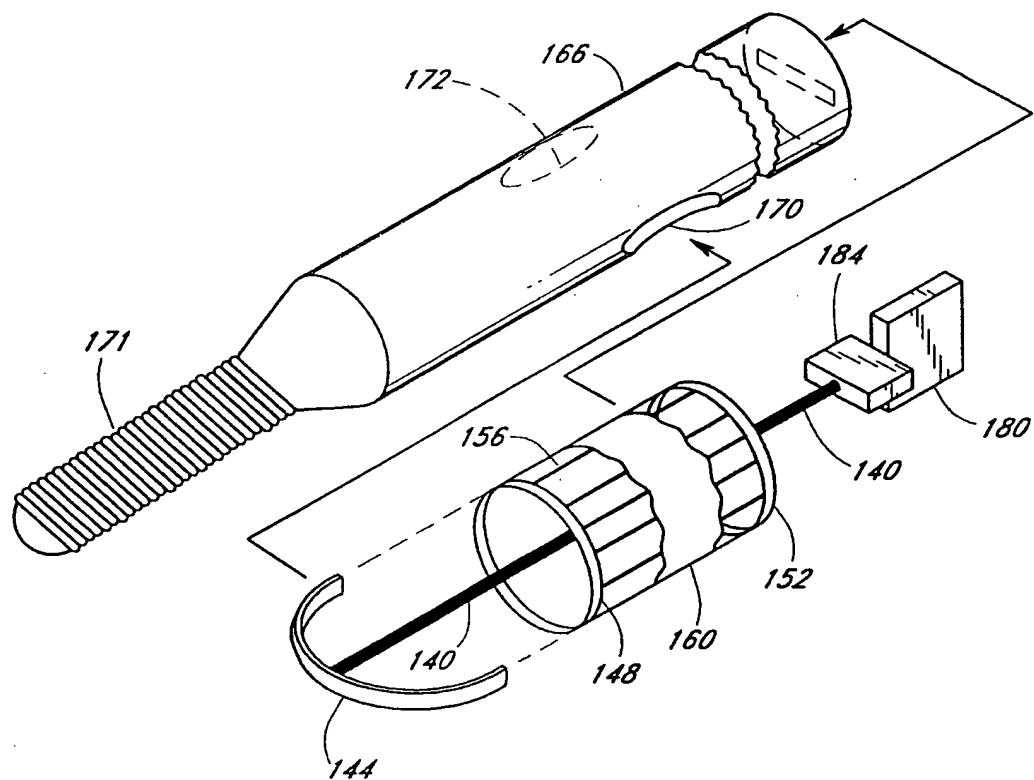


FIG. 15

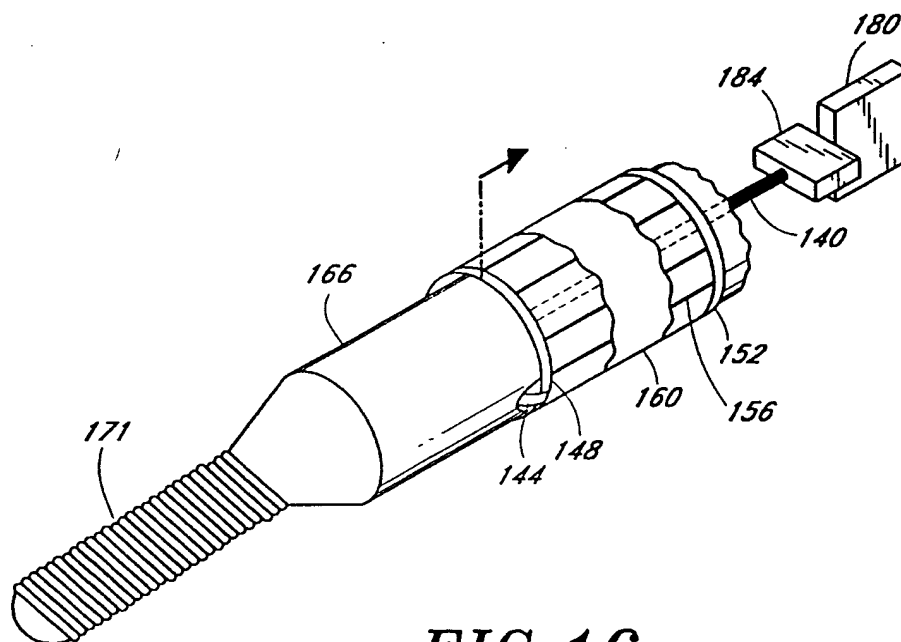


FIG. 16

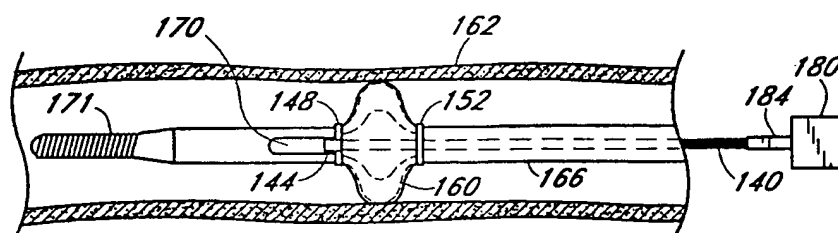


FIG. 17

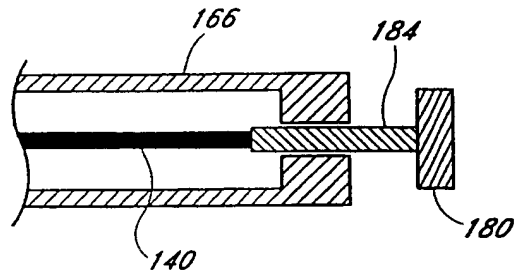


FIG. 18A

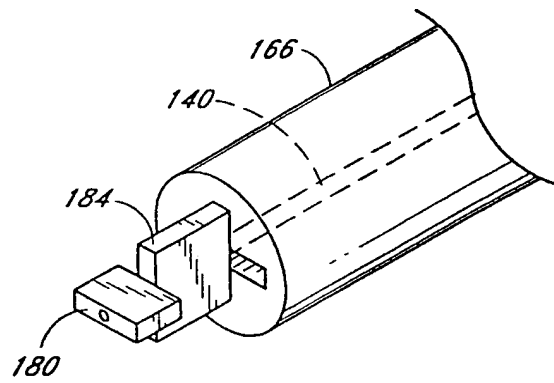


FIG. 18B

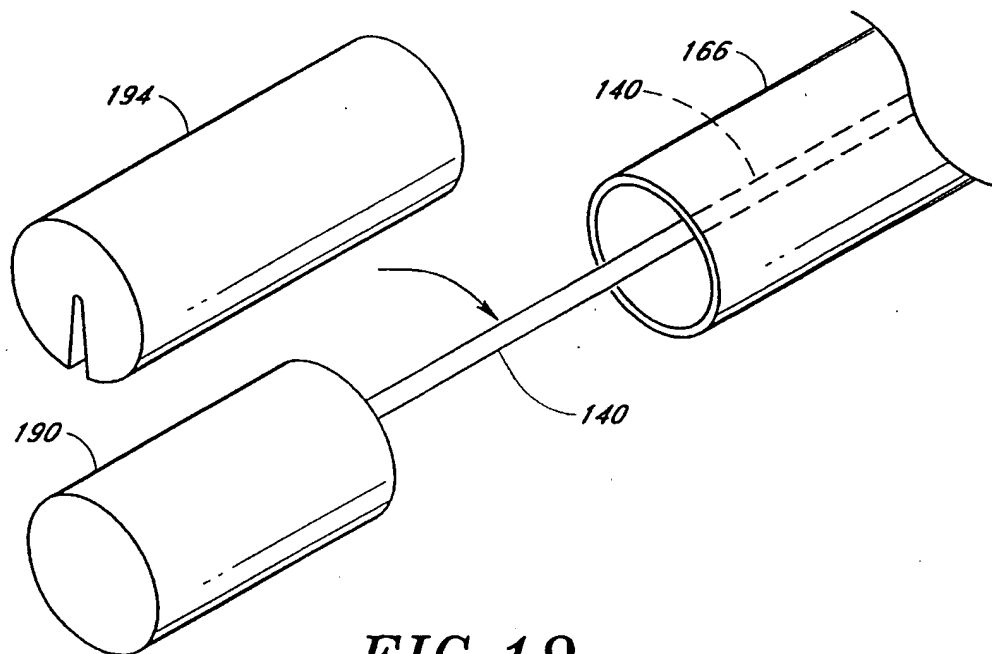


FIG. 19

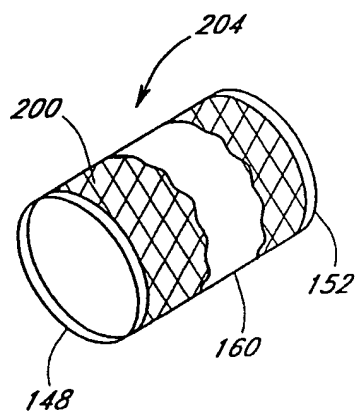


FIG. 20A

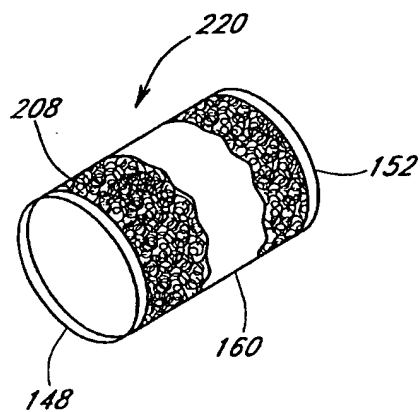


FIG. 20B

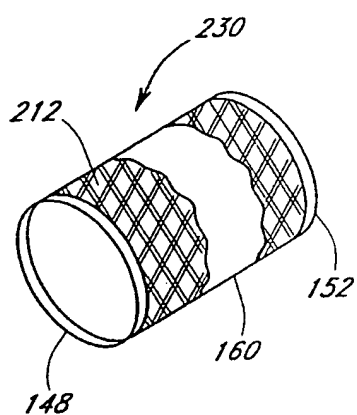


FIG. 20C

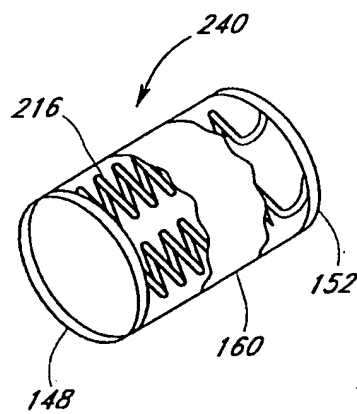


FIG. 20D

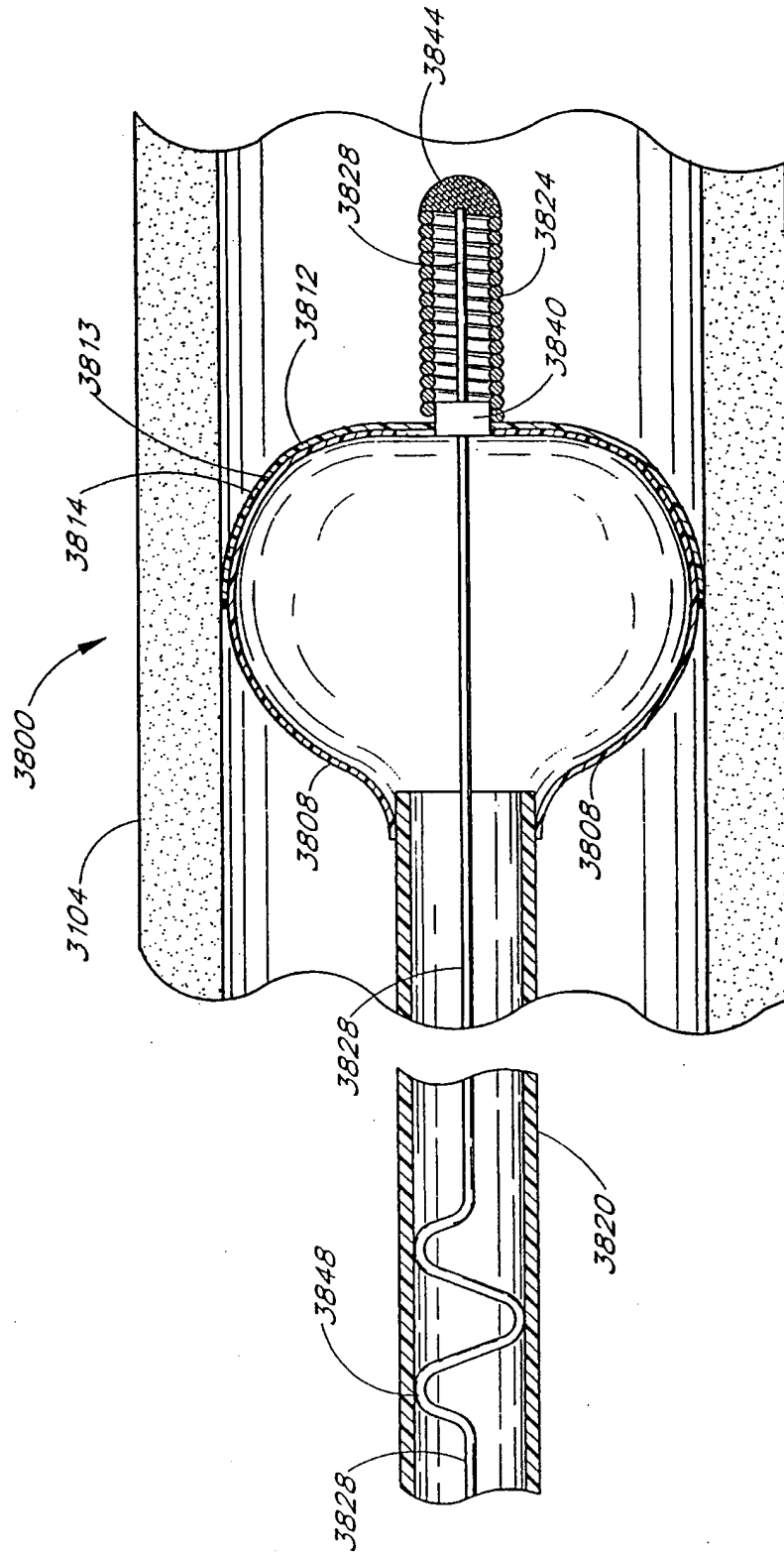


FIG. 21

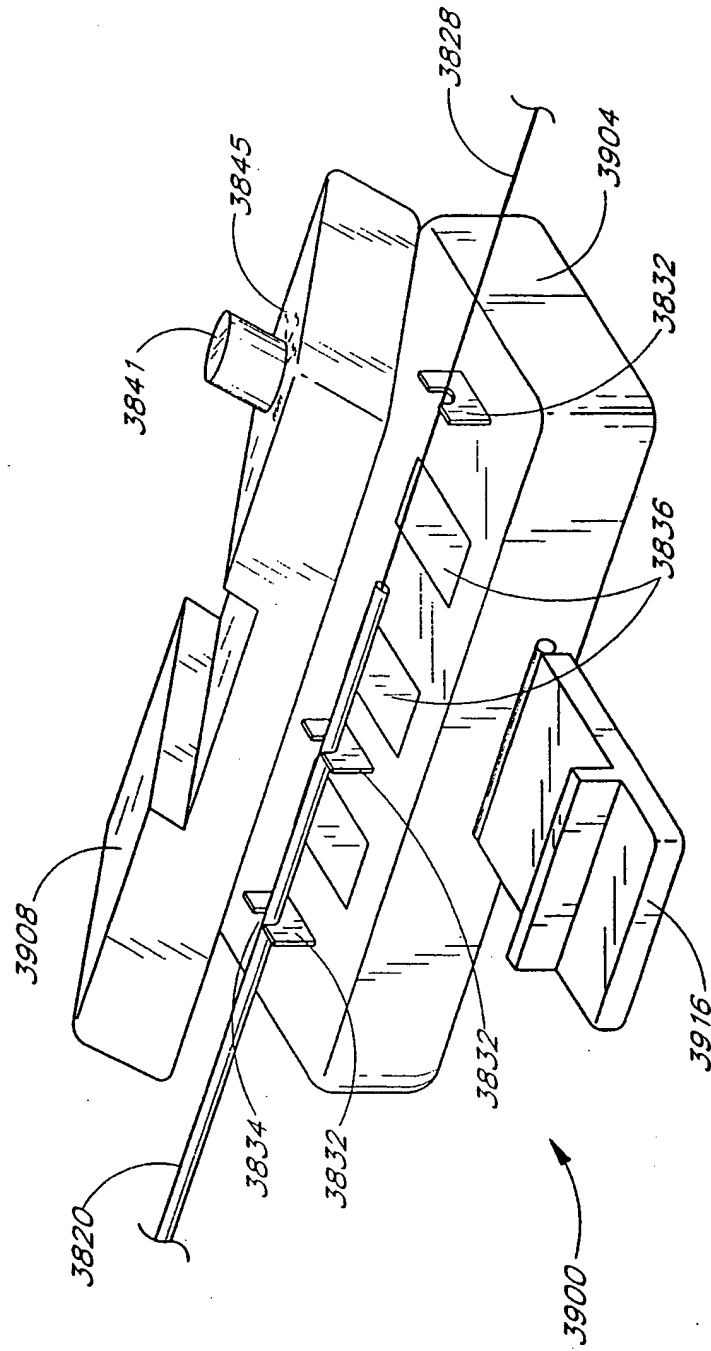


FIG. 22

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/21645

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/01 A61B17/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 321 912 A (DELSANTI) 28 June 1989 (1989-06-28) column 3, line 52 -column 5, line 1; figures 1-3	1,3,4,9, 11,13
Y	US 5 497 782 A (FUGOSO) 12 March 1996 (1996-03-12) abstract; figures 3,3A	1,3,4,9, 11,13
A	US 5 573 508 A (THORNTON) 12 November 1996 (1996-11-12) column 7, line 37 - line 57; figures 8,9	1,4
A	WO 99 02093 A (SCIMED LIFE SYSTEMS, INC.) 21 January 1999 (1999-01-21) the whole document	1,4

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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- *G* document member of the same patent family

Date of the actual completion of the international search

15 November 2000

Date of mailing of the international search report

22/11/2000

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/21645

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